Midwestern Consortium
Division of Survey and Certification

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refer to: N6
Provider Number: 23-0105

January 13, 2004
(via Certified Mail)

Thomas Mroczkowksi
Chief Executive Officer
Northern Michigan Hospital
416 Connable Avenue
Petoskey, MI 49770

Dear Mr. Mroczkowski:

The Centers for Medicare and Medicaid Services has received the report of the December 11, 2003 substantial allegation survey conducted by the Michigan Department of Community Health, Bureau of Health Systems. Based on our review of the survey findings, we have determined that Northern Michigan Hospital is not in compliance with the following Medicare Condition of Participation for Hospitals:

Infection Control 42 CFR 482.42

We have determined that the deficiencies cited are significant and limit your hospital's capacity to render adequate care and to ensure the health and safety of your patients. Enclosed is a complete listing of all deficiencies cited.

In accordance with Section 1865 of the Social Security Act and implementing regulations at 42 CFR 488.5, a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is deemed to meet Medicare Conditions of Participation with the exception of utilization review. Section 1864(c) of the Act requires the Secretary of Health and Human Services to survey an accredited hospital participating in Medicare if there are allegations which suggest the existence of significant deficiencies which would adversely affect the health and safety of patients.

If, in the course of such a survey, the hospital is found to not meet one or more Conditions of Participation and significant deficiencies exist, Section 1865(b) of the Act provides that a hospital is no longer deemed to meet the Medicare Conditions of Participation. With notification to the accrediting body, the hospital is then placed under the survey jurisdiction of the State survey agency until the hospital is found in compliance with all Medicare Conditions of Participation.

Therefore, based on the determination that your hospital does not comply with the above Condition and that a significant deficiency exists, your hospital is no longer deemed to meet the Medicare

Conditions of Participation and is now under the survey jurisdiction of the Michigan Department of Community Health, Bureau of Health Systems.

We have authorized the Michigan Department of Community Health, Bureau of Health Systems to conduct a survey of your facility to assess compliance with the remaining Medicare Conditions of Participation. After the survey is conducted, we will determine if any additional Conditions are not met. Your hospital is subject to termination from the Medicare program for noncompliance with the Medicare Conditions of Participation. We will notify you of our determination.

Under Federal regulation 42 CFR 498.3(d)(9), removal of deemed status is an administrative action, not an initial determination by the Secretary and, therefore, formal reconsideration and hearing procedures do not apply.

We have advised the JCAHO of our determination. If you have any questions regarding this matter, please contact me in our Chicago Office at (312) 886-5344 or Chaya Kaplan-Schoenberg, a member of my staff, at (312) 886-5212.

Sincerely,

/s/
Robert P. Daly, Manager
Non-Long Term Care Branch

Enclosure

cc: Joint Commission on Accreditation of Healthcare Organizations
Michigan Department of Community Health, Bureau of Health Systems (MI00002429)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	230105	A. BUILDING _____ B. WING _____	C 12/11/2003

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A 000	INITIAL COMMENTS Surveyor: 15196 State Facility Number: 240030 Intake Number: MI00002429 Investigation Number: KFQU11 This survey was for the purpose of a Complaint Investigation. The Department surveyors indicated below have evaluated this facility and have found the stated deficiencies to be those Licensure and/or Federal Certification requirements not in compliance on the dates indicated. The following surveyors conducted this survey: Valerie Belcher, RN, MSA #15196 Shirley Tuggle, RN, MSN #02951 Jacqueline Lewis, RN #02538 For the Department's use only - Statement of Deficiencies. _____ Darryl Horton Date Director For the Department's use only - Plans of Correction. I have reviewed the facility's Plans of Correction and	A 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 000	Continued From page 1 have made the following determination: ___Acceptable as written ___Acceptable, subject to noted modifications ___Not acceptable _____ Darryl Horton Date Director	A 000		
A 083	482.23(b)(3) ELEMENT of STANDARD STAFFING AND DELIVERY OF CARE A registered nurse must supervise and evaluate the nursing care for each patient. This ELEMENT is not met as evidenced by: Surveyor: 15196 Based on interview and record review, the facility failed to evaluate the nursing care for 2 (#2 and #3) of 2 patients with pressure sores in the Rehab Unit. Findings include: Record review revealed that patient #2 was admitted on 11/28/03 with paraplegia. An initial pressure sore assessment was done upon admission along with pictures of affected area taken. It was noted that no further evaluation of the pressure sore was documented. Patient # 3 was admitted 11/21/03 with a leg amputation and had only an initial assessment and no further evaluation of pressure areas documented as of 12/9/03. Interview on 12/9/03 with the Contract Nurse and Program Director with the medical records, revealed no further staging, or sizing, or depth evaluation of the pressure sore areas as of survey date	A 083		

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A 083	Continued from page 2 12/9/03. The policy and procedure on pressure ulcers documented that a reassessment was to be done every 5 days and documented on the DecubUlcer/Wound Assessment Flowsheet. This was not done on either patient. [15196]	A 083		
A 084	482.23(b)(4) ELEMENT of STANDARD STAFFING AND DELIVERY OF CARE The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. This ELEMENT is not met as evidenced by: Surveyor: 15196 A 84 Based on record reviews on 12/9/03, during the initial tour, 2 (#9, #20) of 20 patients did not have care plans. Findings include: Patient #9 admitted 12/2/03 and had surgery, did not have a care plan completed. Patient #20 admitted 10/12/03, discharged 10/14/03, and did not have a care plan developed during his hospital stay. [02951]	A 084		
A 087	482.23(c) PREPARATION & ADMINISTRATION OF DRUGS Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under Section 482.12(c), and accepted standards of practice. This STANDARD is not met as evidenced by:	A 087		

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A 087	Continued From page 3 Surveyor: 15196 Based on observation, interview and record review, insulin was not administered according to physician order or standard of care for 1 (#16) of 1 drug error reports reviewed involving insulin. Findings include: Patient # 16 had an order for Insulin 40 units and was only given 20 units per the incident report. The Nurse Manager was interviewed on 12/10/03 regarding the process of administering insulin and reporting of the medication error to the attending physician. The Nurse Manager stated that the Nurse had failed to double check the insulin dose with another Nurse as per facility policy. Double check of insulin doses (a high risk medication) with another Nurse is also a standard of care. Further, the Nurse and Manager had failed to notify the attending physician of the error that day. [15196]	A 087		
A 089	482.23(c)(2) ELEMENT of STANDARD PREPARATION & ADMINISTRATION OF DRUGS All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under Section 482.12(c). This ELEMENT is not met as evidenced by: Surveyor: 15196 A 89 Based on interview and record review, 4 (#4, #5, #6, #7) of 20 sampled patients did not have verbal orders signed by the physician by the next day according to facility policy. Findings include: Patient #4 had verbal orders for Dopamine 3 mcg per minute on 12/3/03 and verbal orders on 12/6/03	A 089		

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A 089	Continued From page 4 Refludan 8 mg IVP now, which had not be authenticated as of 12/9/03. Patient #5 had an order on 12/5 to start an insulin drip now, which had not been authenticated. Patient #6 had a verbal order for Valium 5 mg IVP, which had not been authenticated. Interview with the staff Nurse and Nurse Managers on 12/9/03 revealed that "the physicians were supposed to sign verbal orders the next day." The Administration of Medication policy and procedure documented that verbal orders must be authenticated by the prescribing practitioner by the next day. [15196] Review of the medical record for patient #7 revealed that medication orders of 12/5/03 and 12/06/03 had not been authenticated as of 12/9/03. Interview with the Nurse Manager of 2 North on 12/9/03 revealed that verbal orders should have been signed by the physician at the next visit. [02951]	A 089		
A 123	482.25(b)(3) ELEMENT of STANDARD DELIVERY OF SERVICES Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. This ELEMENT is not met as evidenced by: Surveyor: 15196 Based on observation and interview, it was determined that the facility failed to ensure that outdated or mislabeled drugs were not available for patient use. Findings include: During tour of the Intensive Care Unit and 2 North on 12/9/03, it was noted that insulins were stored unrefrigerated in patients' medication drawers. The insulins were multidose vials that were opened and did not have an updated expiration date (30 days or less when open and unrefrigerated). Interview with the Nurse Managers revealed that multidose vials of	A 123		

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A 123	Continued From page 5 insulin are not dated with an updated expiration date. The facility continues to use the manufacturer's expiration date that applies to unopened and refrigerated medications. [15196, 02951]	A 123		
A 243	482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This CONDITION is not met as evidenced by: Surveyor: 15196 The facility failed to provide an active infection control program to address sources and transmissions of infections and communicable diseases. Findings include: 1) Failure to identify the responsible staff who were to initiate isolation therapy. See A244. 2) Failure to monitor contract staff TB health status. See A245. 3) Failure to provide monitoring/surveillance and timely interventions for problem areas. See A249.	A 243		
A 244	482.42(a) ORGANIZATION AND POLICIES A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. This STANDARD is not met as evidenced by: Surveyor: 15196	A 244		

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A 244	Continued From page 6 A 244 Based on interview and record review there was no indication of who could initiate isolation precautions for droplet and contact isolation precautions. Findings include: Patient #15 was admitted 12/8/03 with pneumonia. Based on interview conducted the 12/9/03 with the nurse and the family, the patient was placed in isolation on the morning of 12/9/03 for positive influenza A. A nasal washing was obtained for RSV Influenza on 12/8/03 at 19:00 (7:00 p.m.). The specimen results were positive for Influenza A and was reported to personnel on 12/8/03 at 20:56 (8:56 p.m.). The report also documented "According to NMH policy IC 116, this patient may be a candidate for droplet precautions." There was no documentation in the medical record of when the isolation was initiated. There was no physicians order or indication when isolation was initiated or by whom. There was no documentation by the staff nurse or the infection control practitioner that the patient was being maintained on droplet precautions. Additionally, review of the infection control policies and procedures revealed inconsistencies regarding who could initiate isolation precautions. Policies and procedures for MRSA (Methicillin Resistant Staphylococcus aureus) and VRE (Vancomycin Resistant Enterococci) as well as TB (Tuberculosis) outline no physician order was required to initiate isolation precautions. It was unspecified who could initiate isolation with other communicable diseases requiring isolation. [02538]	A 244		

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A 245	Continued From page 7	A 245		
A 245	482.42(a)(1) ELEMENT of STANDARD ORGANIZATION AND POLICIES The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This ELEMENT is not met as evidenced by: Surveyor: 15196 A 245 Based on interview and review of employee files, the Infection Control Practitioner failed to develop policies and procedures to prevent the spread of communicable diseases for contract personnel. Findings include: Review of 4 of 8 personnel files for contract staff related to TB revealed no documentation of current TB screening results as required by the facility employee policy. Employee A's last Chest X-ray (CXR), due to previous positive PPD, was dated 7/01. Employee B's last PPD was 05/02, Employee C's last CXR was 6/01, and Employee D's last PPD was 10/31/02. As of 12/10/03 there was no documentation of current TB screening outcomes. Interview with Human Resource (HR) staff on 12/10/03, revealed that HR only maintained screening documentation on hospital employees and not on contract staff. Interview with the Infection Control Practitioner (ICP) on 12/10/03, determined that the ICP was not responsible for monitoring contract staff for TB or TB screening. [02951]	A 245		

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A 249	Continued From page 8	A 249		
A 249	482.42(b)(2) ELEMENT of STANDARD RESPON. OF CEO, MEDICAL STAFF, & D.N.S. The chief executive officer, the medical staff, and the director of nursing services must be responsible for the implementation of successful corrective action plans in affected problem areas. This ELEMENT is not met as evidenced by: Surveyor: 15196 A 249 Based on interview and review of infection control data, the Infection Control Practitioner (ICP) failed to document actions/remedial actions and follow-up of identified problem areas. Findings include: On 12/10/03 review of ICP round sheets indicate names of potentially infectious patients. Many of the patients had no disposition or outcome from the ICP review. The ICP indicated that the worksheets were not permanent and were destroyed after review. Therefore there was no way to determine if the facility's system for identifying and monitoring was effective. The ICP had no documentation of follow-up of recommendations made on identified problem areas. Interview with the ICP, Surgery Nurse Manager, Quality Improvement Director and Risk Manager on 12/10/03 and 12/11/03, revealed that the facility was aware of a flash sterilization problem in 11/02. During 2003, the ICP monitored to see if flash sterilization strips with all required information was recorded. Monitoring logs for the year revealed poor compliance i.e., 11 of 15 observations did not have required documentation to signify that all process checks for flash sterilization were completed. The ICP stated that she notified the Surgery Manager as well as the Medical Directors of Epidemiology and Surgery, but there was no documentation to support any notification	A 249		

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A 249	Continued From page 9 or intervention in early 2003. Poor compliance with flash sterilization documentation continued for most of 2003. No monitoring was done in 8/03 or 10/03. In 8/03, and again on 10/27/03, an issue was identified with flash sterilization not being completed. For both instruments, forceps and camera, documentation revealed inadequate length of time for proper sterilization and subsequently patients were placed at risk for infection. [15196, 02538]	A 249		